



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/525,633

04/10/2006

Ozkan Yalkinoglu

Le A 36 293

3695

35969

7590

03/24/2010

Barbara A. Shimei

Director, Patents & Licensing

Bayer HealthCare LLC - Pharmaceuticals

555 White Plains Road, Third Floor

Tarrytown, NY 10591

EXAMINER

BASS, DIRK R

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

03/24/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/525,633	Applicant(s) YALKINOGLU ET AL.	
	Examiner DIRK BASS	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-16 is/are pending in the application.
- 4a) Of the above claim(s) 2, 9 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-5, 7-8, 11-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response filed November 26, 2009 is acknowledged. Claims 1-8 and 11-16 are pending. Claims 1, 3, 4 are amended, claim 6 is cancelled, and claims 2, 9, and 10 are withdrawn from consideration. Claims 1, 3-5, 7-8, and 11-16 are further considered on the merits.

Response to Amendment

In light of applicant's amendments, the examiner modifies the grounds of rejection set forth in the office action dated August 26, 2009.

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. **Claims 1, and 3-4** are rejected under 35 U.S.C. 103(a) as being unpatentable over Landfield et al., USPA 2005/0071088 (Landfield).
3. Regarding claims 1 and 3-4, Landfield discloses a method of assessing a state of Alzheimer's disease (abstract and ¶ 0006) comprising detecting neurosecretory protein VGF (¶ 0114, Claims 1 and 32).
4. Landfield fails to explicitly disclose the molecular mass of VGF. However, VGF, also referred to as marker 1 in applicant's specification (pg. 6, l. 6 and Table 1), is shown by applicant to have varying molecular masses dependent upon surface materials used during SELDI-TOF analysis (pg. 23, l. 17, 26, and pg. 24, l. 1). Therefore, the examiner considers such a molecular mass to be a result effective variable, based on methodology during SELDI-TOF analysis.
5. At the time of invention, it would have been obvious to one skilled in the art to modify the method of Landfield to detect neurosecretory protein VGF having a molecular mass of 4824 Da since it has been held that discovering the optimum value of a result effective variable involves only routine skill in the art (MPEP 2144.05, Section II, Part B).

Art Unit: 1797

6. Furthermore, while Landfield does not explicitly disclose detecting applicant's recited sequence ID # 17, Landfield discloses detecting a polypeptide sequence of neurosecretory protein VGF (Claims 1 and 32). Therefore, the claim would have been obvious because "a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense." (MPEP 2141, Section III, Part E).

7. **Claims 5, 7-8, and 11-16** are rejected under 35 U.S.C. 103(a) as being unpatentable over Delacourte et al., USPA 2005/0175626 (Delacourte) in view of Landfield as relied upon above.

8. Regarding claims 5, 7-8, and 11-16, Delacourte discloses a method of assessing a state of Alzheimer's disease (Claim 1) comprising separating polypeptides from cerebral spinal fluid samples via antibodies specific for said polypeptides and detecting said polypeptides via SELDI-TOF MS (see Example 3, ¶ 0207-0210).

9. Delacourte fails to explicitly disclose a method wherein the polypeptide being detected is neurosecretory protein VGF. However, Landfield discloses a method of assessing a state of Alzheimer's disease (abstract and ¶ 0006) comprising detecting neurosecretory protein VGF (¶ 0114, and claims 1, 32).

10. At the time of invention, it would have been obvious to one skilled in the art to use the neurosecretory protein VGF disclosed in Landfield in the method of Delacourte because all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Response to Arguments

11. Applicant's arguments with respect to claims 1, 3, and 4 have been considered but are moot in view of the new ground(s) of rejection.

Art Unit: 1797

12. Furthermore, applicant argues that Landfield discloses a method wherein neurosecretory protein VGF has a molecular weight larger than the currently claimed molecular mass for the marker. In response, the examiner directs applicant's attention to the rejection of claim 1 set forth above. The examiner points out that applicants derive multiple molecular mass values for the same marker protein, each produced through a different analysis method. This is relied upon as evidence that selecting such a molecular mass is a result effective variable, one which applicant could have routinely optimized to achieve the best results.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIRK BASS whose telephone number is (571) 270-7370. The examiner can normally be reached on Mon - Fri (9am-4pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1797

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DRB/
Dirk R. Bass

/Angela Ortiz/

Supervisory Patent Examiner, Art Unit 1797